

**WAC 246-885-030 Over-the-counter (OTC) drug imprint regulation.**

(1) Pursuant to the provisions of RCW 69.60.090, chapter 69.60 RCW will cease to exist in its entirety upon implementation by the federal Food and Drug Administration (FDA) of provisions regulating solid dosage imprinting of OTC medications and upon a finding by the Washington state board of pharmacy that the FDA regulations are substantially equivalent to those in chapter 69.60 RCW.

(2) The FDA adopted a final rule regarding OTC solid dosage imprinting, codified in 21 C.F.R. 206.01-10. This rule became effective September 13, 1995. The applicability of the federal rule is limited to those products introduced into interstate commerce on or after the effective date of the regulation. The rule is inapplicable to those noncompliant products introduced into interstate commerce prior to the effective date and to those products pending FDA review and approval of applications submitted by the manufacturer.

(3) The board finds that the inapplicability of the FDA rule to noncompliant products introduced into interstate commerce before the effective date and to those products currently on the market would permit the sale of these products in the state of Washington and thus fails to adequately protect the citizens of the state of Washington.

(4) Therefore, notwithstanding the provisions of 21 C.F.R. 206.1 et seq. no nonimprinted solid dosage form drug that is intended for OTC sale may be distributed into or sold in the state of Washington unless it has been found by the board to be exempt from the provisions of this chapter or has received an exemption from the FDA pursuant to 21 C.F.R. 206.7. Copies of official documents that support such exemptions shall be filed with the board prior to any distribution of the nonimprinted product(s).

[Statutory Authority: RCW 18.64.005. WSR 96-07-012, § 246-885-030, filed 3/11/96, effective 4/11/96.]